

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

TARA STEFANI and TANYA VILLANUEVA,  
as individuals, on behalf of themselves, and others  
similarly situated,

Plaintiffs,

v.

23ANDME, INC.,

Defendant.

Case No.

**JURY TRIAL DEMANDED**

Plaintiffs Tara Stefani (“Plaintiff Stefani”) and Tanya Villanueva (“Plaintiff Villanueva”) (together, “Plaintiffs”) allege the following upon personal knowledge as to their own transactions and upon information and belief (based upon, inter alia, investigation conducted by their attorneys) as to all other matters.

**INTRODUCTION**

1. This class action concerns false, misleading and improper representations, and advertisements and promises made by 23andMe, Inc. (“Defendant” or “23andMe”) concerning its DNA Saliva Collection Kit/Personal Genome Service (“Saliva Kits”). For the cost of \$99.00, until on or about December 6, 2013, 23andMe suggested that, upon receiving a submitted DNA saliva sample from a customer through the mail, it could provide accurate health information (the “Health Information”), such as the subject’s status as a carrier of certain genetic traits, health risks, and potential drug responses. 23andMe made these promises without providing any scientific or clinical validation that its Saliva Kits are accurate, reliable or fit for their advertised uses. 23andMe’s Saliva Kits have never received marketing authorization or approval from the Food and Drug Administration (“FDA”). Ignoring this vital requirement and in violation of the Federal Food, Drug and Cosmetic Act (“FDC Act”), until on or about December 6, 2013,

23andMe continued to market, advertise, promote and sell its Saliva Kits in violation of the FDA's marketing standards for such products.

2. In addition to misleading unsuspecting consumers who purchased Saliva Kits, 23andMe illegally collects submitted statistical information it receives from its customers and markets it to the scientific community for unknown uses.

3. As a result of 23andMe's improper and unlawful conduct, countless consumers and end-users, who relied on Defendant's representations and statements as being truthful and accurate, have been deceived, wronged, and financially harmed.

### **JURISDICTION AND VENUE**

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2), because Plaintiff Stefani and over two-thirds of the Class Members are of diverse citizenship from the Defendant and the aggregate amount in controversy exceeds five million dollars (\$5,000,000.00) exclusive of interest and costs.

5. Venue is proper in this district pursuant to 28 U.S.C. §1391 because a substantial part of the events or omissions giving rise to Plaintiff Stefani's claims occurred here, a substantial part of the property that is the subject of this action is situated here, and Defendant is subject to personal jurisdiction in this District.

6. As a result of Defendant's designing, testing, developing, manufacturing, distributing, advertising, promoting and/or selling of Saliva Kits to purchasers throughout Massachusetts, Defendant obtained the benefits of the laws of Massachusetts as well as California.

7. Defendant conducted systematic and continuous business activities in and throughout the Commonwealth of Massachusetts and otherwise intentionally availed itself of the markets of the state of Massachusetts through the promotion and marketing of its business.

### **PARTIES**

8. At all times herein relevant, Plaintiff Tara Stefani was and is a resident of Hingham, Massachusetts.

9. Plaintiff Villanueva is a resident of Oakland, California.

10. Defendant 23andMe, Inc. is a Delaware corporation founded in 2006. It is headquartered in Mountain View, California and conducts business in the Commonwealth of Massachusetts, the State of California, and throughout the United States.

## **FACTUAL ALLEGATIONS**

### **A. DEFENDANT'S BUSINESS**

11. Defendant 23andMe advertises, markets, and sells its Saliva Kits directly to consumers through print, on-line means, radio, and other similar marketing vehicles.

12. Defendant claims that its Saliva Kits act as an accurate and reliable DNA genetic test.

13. Upon receiving a submitted sample from a customer, Defendant boasted that it conducts DNA testing for over 240 “conditions” and traits.

14. Upon determining the purported results, using unknown testing conditions and means, Defendant sent a status report to customers which it claimed to be accurate.

### **B. PLAINTIFFS' TRANSACTIONS**

15. In December 2013, Plaintiff Stefani purchased a Saliva Kit for \$108.95 (\$99 plus shipping and handling).

16. Plaintiff Stefani ordered the kit relying on Defendant's statements concerning its purported ability to determine and predict DNA related-traits, family characteristics and general health.

17. Plaintiff Stefani had no reason not to believe Defendant's representations.

18. Upon purchasing her kit, Plaintiff Stefani received an e-mail from Defendant confirming her “Personal Genome Service” order. Although the email stated that she was purchasing ancestry-related information without the Health Information, she believed that 23andMe would offer the Health Information to her as soon as the FDA authorized 23andMe's marketing. Relying on this belief, she paid the same price for the ancestry-related information as

she would have for the Health Information and ancestry-related information together. 23andMe did not offer her a refund or discount for the results that the FDA prohibited it from transmitting.

19. To date, almost one month after the FDA issued its November 22, 2013 Warning Letter to 23andMe, it has still not authorized 23andMe to market the provision of Health Information. 23andMe did not inform its customers of the seriousness of the FDA's concerns or post the FDA Warning Letter on its website. As a result, there was no way for Plaintiff Stefani to know that 23andMe's DNA testing was seriously flawed and lacked sufficient scientific foundation. Upon learning of the seriousness of the FDA's concerns, Plaintiff Stefani began to distrust the accuracy of the results of all of 23andMe's tests.

20. Plaintiff Stefani would not have purchased the Saliva Kit had she known of the seriousness of the FDA's concerns about the accuracy of the Saliva Kit.

21. On or about September 5, 2013, Plaintiff Villanueva purchased a Saliva Kit from 23andMe for \$108.95 (\$99 plus shipping and handling). She relied on 23andMe's advertising and representations that it could provide her with the promised Health Information in conformance with FDA directives. Upon receipt of the results, she was immediately suspicious of the test's accuracy for both ancestry and the health analysis. The ancestry portion was vague and not precise and the "health analysis" seemed "contrived." According to Plaintiff Villanueva's posts on 23andMe's Facebook page:

- a. There were huge areas of undetermined DNA -- approximately 81%, and
- b. with respect to the "health analysis," the client is "questioned" as to health issues, and she believed that results seemed contrived in many cases.
- c. She was only able to contact 23andMe's customer service after posting a comment on Facebook.

22. Having been refused a refund, she filed a dispute with her bank in the hopes that the charges would be reversed.

**C. 23ANDME'S SALIVA KITS VIOLATE THE FEDERAL FOOD, DRUG AND COSMETIC ACT.**

23. Because it cannot provide proof of the validity of its marketing claims to the FDA and has not obtained marketing permission or approval from the FDA, advertising and sale of Defendant's Saliva Kits violate the FDC ACT.

24. On November 22, 2013, the FDA sent Defendant a "Warning Letter" ("FDA Letter", attached hereto as Exhibit A) enumerating various concerns it had with the Saliva Kits and the way Defendant advertised the product. The FDA specifically cited concerns about the public danger involved in false positives and false negatives for serious health conditions purportedly tested by Defendant's kits.

25. The FDA Letter, among other things, stated that "[t]o date, 23andMe has failed to provide adequate information to support a determination that the PGS [Saliva Kits] is substantially equivalent to a legally marketed predicate for any of the uses for which you are marketing it; no other submission for the PGS device that you are marketing has been provided under section 510(k) of the [FDC] Act, 21 U.S.C. § 360(k)."

26. To date, the FDA still has not received any assurance that the Defendant has analytically or clinically validated Saliva Kits for their intended uses.

27. The FDA letter states that: "The risk of serious injury or death is known to be high when patients are either non-complaint or not properly dosed; combined with the risk that a direct-to-consumer test result may be used by a patient to self-manage, serious concerns are raised if test results are not adequately understood by patients or if incorrect test results are reported."

28. As the FDA makes clear in its letter, 23andMe advertised and marketed Saliva Kits to consumers without any analytical or clinical data to support their accuracy or validity. As a result of Defendant's failure to meet FDA standards and requirements, 23andMe posted the following notice to customers on its website (last visited Dec. 8, 2013):

Welcome to 23andMe.

At this time, we have suspended our health-related genetic tests to comply with the U.S. Food and Drug Administration's directive to discontinue new consumer access during our regulatory review process.

We are continuing to provide you with both ancestry-related genetic tests and raw genetic data, without 23andMe's interpretation.

If you are an existing customer please click the button below and then go to the health page for additional information, including information about refunds.

We remain firmly committed to fulfilling our long-term mission to help people everywhere have access to their own genetic data and have the ability to use that information to improve their lives.

Nowhere does the notice indicate the seriousness of the FDA's concerns about validity of 23andMe's testing for health-related conditions.

**D. DEFENDANT'S FALSE AND MISLEADING REPRESENTATIONS CONCERNING PURPORTED HEALTH BENEFITS.**

29. Defendant represented and advertised that the results of Saliva Kit tests would improve consumers' health. Until on or about December 2013, Defendant stated the following on its website:

- a. "Learn hundreds of things about your health. Using your DNA information, 23andMe helps you know more about your health so you can take an active role in managing it. With reports on over 240+ health conditions and traits, here are a few of the things you'll learn about you."
- b. "Plan for the future. Find out if your children are at risk for inherited conditions, so you can plan for the health of your family."
- c. "Living well starts with knowing your DNA."
- d. "Health tools - Document your family health history, track inherited conditions, and share the knowledge."
- e. "Drug response - Arm your doctor with information on how you might respond to certain medications."
- f. "Below are a few examples [diabetes, arthritis, coronary heart disease, breast

cancer, plavix, lactose intolerance] where we can help you learn more. And when you know more, you can make better lifestyle choices, look out for common conditions and take steps toward mitigating serious diseases.”

30. Defendant’s statements about the health benefits of its DNA testing went as far as to state:

23andMe is a DNA analysis service providing information and tools for individuals to learn about and explore their DNA. We use the Illumina HumanOmniExpress-24 format chip . . . . Our chip consists of a fully custom panel of probes for detective single nucleotide polymorphisms (SNPs) selected by our researchers. The selection was made to maximize the number of actionable health and ancestry features available to customers as well as offer flexibility for future research.

31. To the contrary, the Saliva Kits worked to confuse customers as to their health and possibly cause adverse health reviews and diagnoses. For instance, on May 14, 2008, Dr. Rudolph Tanzi, a professor of neurology at Harvard University and director of the Genetics and Aging Research Unit at Massachusetts General Hospital, testified before the United States Senate Special Committee on Aging about the dangers of Defendant’s product, stating as follows in response to a question from then-Senator Hillary Rodham Clinton:

[I]t should be noted that companies like 23andMe, Navigenics, Knome, and DeCode are already charging considerable sums of money for anyone who wishes to pay to be tested for the “unconfirmed” genetic risk factors for Alzheimer’s and other common diseases, e.g. cardiovascular disease, cancer, and stroke. In my view, it is highly premature and both medically and commercially irresponsible to be conducting these tests. To reliably predict disease risk, we will first need to establish the full set of “confirmed” risk factors and then determine how they work together to influence risk in a “multigenic” manner. As these companies become more popular, the public will need to be increasingly informed and educated about the fact these tests are not yet accurate, reliable, or scientifically sound. I am concerned that these tests may increasingly lead to unwarranted anxiety or a false sense of security about one’s genetic destiny as these companies services become more “trendy.”

32. Defendant’s health assertions, statements, and representations were unfounded and not supported by any scientific research or factual basis.

**D. DEFENDANT’S FALSE AND MISLEADING ADVERTISEMENTS AND REPRESENTATIONS.**

33. From approximately 2009 until December 6, 2013, Defendant marketed and advertised its Saliva Kits as being beneficial and useful for health-related purposes despite having no scientific data or research to support the claims.

34. As late as January 2013, in response to an FDA inquiry, 23andMe was still “completing the additional analytical and clinical validations for the tests that have been submitted” and “planning extensive labeling studies that will take several months to complete.”

35. Consumers would not have purchased the Saliva Kits if they knew that Defendant’s representations were false and that the product was not sanctioned by the FDA.

36. Defendant was and is aware of the misleading nature of its product as demonstrated by the following Internet consumer complaints:

I also found both the so called health analysis to be pretty much useless. Sure, you’re told that people with your genetic markers have a higher percentage than others markers of a certain disease or health risk, but so what? That is totally meaningless as lifestyle, diet, excercise [sic] and a host of other factors come into play and serve a far more important determination of what kind of health you have and are going to have. I didn’t expect a lot from this test- but perhaps something a little more defined than what this offers. In addition, there [are] a TON of very personal surveys and questions they ask you (optional of course) - some of which seem to [be] written by very bored college research interns. In my opinion, unless you have no idea what your racial makeup is and no clue about where modern humans originate from, don’t waste your money on this.

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I heard that you also need to enroll (mandatory) for ten months and pay \$5/mo to keep your page going. Too many complaints about CS, ghost Co. overseas? Results are just a general idea generated by a PC software....if it is CHEAP, don’t expect true good results! Also seems like they fail to disclose that your “controversial” information may be leaked (sold?) to the Health and Insurance Companies to use for review when you apply for services, don’t waste your money and loose your personal information at same time...STAY AWAY.

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23andme charged me \$395 for my DNA analysis. They only analyzed my DNA to a certain point, saying they have not analyzed my branch of DNA any further (I guess it was not beneficial to the woman, the wife of a GOOGLE founder, to learn any more about this genetic profile). They then asked me to pay them MORE money if I wanted to learn about my genetic predisposition to getting Alzheimer's. I wanted to see if I had any relatives in the world, since all of my relatives except my parents were killed in the Holocaust, but they have a very low user rate, so the chances of finding a close relative are almost nil. If you want to get your DNA analyzed, I strongly recommend you try one of the companies offering this service.

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Even after sending me a replacement test they can't read my DNA. They are offering to refund the money I paid for the test but offered NO explanation as to why they couldn't read it. I followed the directions to the letter both times. This concerns me.

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Not worth the risk of a very questionable study. The Terms of Agreement are invasive and not like any requirements for a legitimate study. I was very concerned about my private information, how it would be used, and to whom it would be made available.

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I paid \$299 for the kit 8 months ago. It is now being offered for \$99 and based on other reviews, has been offered for that price in the past. Is [it] worth \$299? Absolutely not! Will they offer you a partial refund? Absolutely not! The genealogy information is very general. It may be because they do not have a big enough database to offer more detailed information. The information concerning health risks while interesting was not entirely accurate. In my own case, I have had a couple of serious health conditions that were listed as very low risk for me. I have to wonder how accurate the other results are.

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I think this is a scam.... They took a sample, and after two months, I find out that they could not get DNA from the sample, and sent me another kit. A month later, they tell me that they couldn't get DNA, and will refund my money "less shipping costs"

So, they keep the shipping costs, I lost months of time waiting, and have nothing to show for it, except a smaller wallet. I don't want my money back -- I want my results!

In the meantime, no help as to trying to find out WHY they didn't get DNA from my saliva... Except that maybe there is no DNA in saliva??? They need skin cells, so why not provide a swab to collect DNA from my cheek? Or offer some other way to do it, other than dropping me and keeping a portion of my money? There is NO place to call for support. They do NOT respond to their emails. Their support level is a JOKE.

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23ANDME is a RIPOFF! RIPOFF! RIPOFF!. It's a SCAM!!! It's a SCAM!!! I bought one of their \$99 test kits that will break down my genetics and tell me my chances of getting ill from certain cancers and heart disease. I could not believe my eyes when I saw the test results. TOTALY FALSE! They make these numbers up! I called them for a refund and I was insulted by Andy Page who refused to return my money. I had my tests done somewhere else and the results were totally different. I called them again and a technician by the name of "Arnab Chowdry" secretly told me that the results are made up and no actual genetic study is done. Anne "The founder of this scam" he told me, made up the idea when they where [sic] dating each other. I want to make myself available for any class action lawsuits against this FRAUD!

37. Further illustrating Defendant's false advertising is Defendant's Terms of Service ("TOS"). Buried within it is the real reason that Defendant is asking consumers to pay \$99.00 to have their DNA analyzed: Defendant plans to create a huge DNA database and resell the data they collect about customers' DNA to third parties.

38. To that end, Defendant's TOS provide that, "in order to expand and accelerate the understanding and practical application of genetic knowledge in health care, we invite all genotyped users to participate in 23andWe Research. Participation in such research is voluntary and based upon an IRB-approved consent document." The TOS defines "23andWe Research" as "scientific research that 23andMe performs with the intent to publish in a peer-reviewed scientific journal. 23andWe Research only uses Genetic and Self-Reported Information from users who have given consent according to the applicable Consent Document. 23andWe Research activities do not include R&D."

39. Despite attempting to obtain this consent from each of its customers, Defendant explains much further in its TOS that they “will not receive compensation for any research or commercial products that include or result from [thei]r Genetic Information or Self-Reported Information.”

40. The TOS describes Defendant’s use of customers’ “Genetic and Self-Reported Information” as follows:

If you have given consent for your Genetic Information and Self-Reported Information to be used in 23andMe Research as described in the applicable Consent Document, we may include your information in the Aggregated Genetic Information and Self-Reported Information we disclose to third parties for the purpose of publication in a peer-reviewed scientific journal. 23andMe may also include your information in Aggregated Genetic and Self-Reported Information disclosed to third-party non-profit and/or **commercial research partners** who will not publish that information in a peer-reviewed scientific journal.

(emphasis added.)

41. Nowhere in the advertising or website does Defendant disclose that this is the real purpose of its DNA testing services.

42. In addition, based on information and belief, in an effort to make its product appealing, Defendant also publishes false “research” reports and studies that lack any statistical or scientific data.

43. Defendant’s representations are misleading, deceptive, and unfair. Defendant’s misrepresentations and practices caused the Plaintiffs and putative Class Members to rely on them and financially injured Plaintiffs and putative Class Members.

### **CLASS ACTION ALLEGATIONS**

44. Plaintiffs seek to bring this case as a class action, under Federal Rule of Civil Procedure 23, on behalf of themselves and all others similarly situated. The proposed Class is defined as:

All individuals and entities who have purchased a 23andMe Saliva Kit in the United States.

Excluded from the Class are Defendant, any entity in which Defendant has a controlling interest or which has a controlling interest of Defendant, and Defendant's legal representatives, assigns, and successors. Also excluded are the judge to whom this case is assigned and any member of the judge's immediate family.

45. Numerosity. The number of persons who are members of the Class described above are so numerous that joinder of all members in one action is impracticable.

46. Commonality and predominance. Questions of law and fact that are common to the entire Class predominate over individual questions because the actions of Defendant complained of herein were generally applicable to the entire Class. These legal and factual questions include, but are not limited to:

- a. Whether Defendant advertised and sold Saliva Kits with knowledge of its unreliability and misleading results;
- b. Whether Defendant's advertising was unfair, deceptive, untrue, or misleading;
- c. Whether the arbitration clause contained in some iterations of Defendant's TOS applies to Class Members and is unconscionable;
- d. Whether Defendant's TOS were adequately disclosed to Class Members;
- e. Whether Defendant's TOS contains unconscionable and/or illusory terms and language;
- f. Whether Defendant obtained appropriate and timely approval from the FDA to market and sell its Saliva Kits;
- g. Whether Defendant's promises of health reports and risks were likely to mislead reasonable and relying consumers;
- h. Whether Class Members are entitled to restitution and other equitable relief requested herein; and
- i. Whether Class Members suffered damages and are entitled to damages.

47. Typicality. Plaintiffs' claims are typical of Class Members' claims. Plaintiffs and the Class Members sustained similar injuries as a direct result of purchasing the Saliva Kits in reliance on Defendant's deceptive advertising and without reliability of results.

48. Adequacy. Plaintiffs will fairly and adequately represent and protect Class Members' interests. Plaintiffs have no interests antagonistic to Class Members. Plaintiffs have retained counsel with experience prosecuting consumer class-action and complex litigation claims.

49. Superiority. A class action is superior to all other available methods for fair and efficient adjudication of this controversy. Plaintiffs know of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action.

50. This action is appropriate. The prosecution of separate actions by individual members of the Class would create a risk of inconsistent and varying adjudications concerning the subject of this action, which adjudications could establish incompatible standards of conduct for Defendant under the laws alleged herein.

### **COUNT I**

#### **Violations of California False Advertising Law CAL. BUS. & PROF. CODE §§ 17500 et seq.**

51. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

52. Defendant is a "person" within the meaning of CAL. BUS. & PROF. CODE § 17506.

53. By representing to the general public, including Plaintiffs and the putative Class Members, that its Saliva Kits allow consumers to "[l]earn hundreds of things about your health," "[f]ind out if your children are at risk for inherited conditions, so you can plan for the health of your family," "[a]rm your doctor with information on how you might respond to certain medications," and learn more about their susceptibility to certain diseases and conditions, Defendant engaged in false and misleading practices prohibited by the California False Advertising Law (CFAL).

54. In addition to being false, Defendant's advertisements and representations are also misleading and have the capacity, likelihood, and tendency to deceive and confuse consumers, including Plaintiffs and the putative Class Members.

55. Defendant knew, or would have known with the exercise of reasonable care that its advertisements and representations about the benefits of its Saliva Kits were false and misleading.

56. Defendant made these false and misleading advertisements and misrepresentations with the intent of inducing consumers to purchase the Saliva Kits.

57. Plaintiffs purchased Saliva Kits in reliance on Defendant's false and misleading advertisements and representations about the product. Plaintiffs would have foregone purchasing Defendant's product had they known that the Saliva Kits were unreliable and did not possess the health and other benefits that Defendant's advertisements attributed to it.

58. As a result of the foregoing acts, omissions, and practices, Plaintiffs and the putative Class Members have suffered actual damages as described herein.

59. Pursuant to Business & Professions Code §§ 17203 and 17535, Plaintiffs seek an order of this Court enjoining Defendant from continuing with the advertisements and representations about its Saliva Kits and requests an order awarding Plaintiffs and the putative Class Members restitution of the money wrongfully acquired by Defendant.

## **COUNT II**

### **Violation of California Unfair Competition Law CAL. BUS. & PROF. CODE § 17200, et seq. ("unlawful" element)**

60. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

61. Defendant is a "person" within the meaning of CAL. BUS. & PROF. CODE § 17201.

62. Defendant unfairly, unlawfully, deceptively, and misleadingly represented what the Saliva Kits could do. Defendants boasted that the kits would allow consumers to "[l]earn

hundreds of things about your health,” “[f]ind out if your children are at risk for inherited conditions, so you can plan for the health of your family,” and “[d]ocument your family health history, track inherited conditions, and share the knowledge,” and learn about various diseases. To the contrary, the Saliva Kits do none of those things and the results it provides are not supported by any scientific evidence or data.

63. Plaintiffs and the putative class purchased Saliva Kits in reliance on Defendant’s unfair, unlawful, deceptive, and misleading representations about the product. Plaintiffs would have foregone purchasing Defendant’s product had they known that the Saliva Kit was unreliable and did not possess the health and other benefits that Defendant’s advertisements claimed.

64. Defendant’s business practices, as alleged herein, are unlawful because they violate the Federal Food, Drug and Cosmetic Act and California law.

65. As a result of the foregoing acts, omissions, and practices, Plaintiffs and the putative Class Members have suffered actual damages as described herein and are entitled to recover such damages, together with punitive damages, equitable relief, injunctive relief and reasonable attorneys’ fees.

66. Pursuant to Section 17203 of the California Business & Professions Code, Plaintiffs seek an order of this Court enjoining Defendant from continuing to engage, use, or employ its unfair and fraudulent practice of advertising the sale and use of the Products and making false claims about the Saliva Kits and requiring Defendant to make full restitution of all monies wrongfully obtained as a result of its conduct.

### **COUNT III**

#### **Violation of California Unfair Competition Law CAL. BUS. & PROF. CODE § 17200, et seq. (“unfair” and “fraudulent” elements)**

67. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

68. Plaintiffs purchased a Saliva Kit in reliance on Defendant’s false and misleading advertisements and representations about the product. Plaintiffs would not have purchased

Defendant's products had they known that the Saliva Kits were unreliable and did not possess the suggested benefits that Defendant's advertisements claimed it has.

69. Defendant's false and misleading representations about the health and other benefits of its Saliva Kits violate long standing public policy in the United States and California prohibiting businesses from claiming a product will provide health benefits without substantiating scientific evidence and/or data.

70. Defendant's false promise that the Saliva Kits will help its customers determine if their "children are at risk for inherited conditions" and "[u]nderstand [thei]r genetic health risks" is improper and unfounded.

71. Defendant knew or should have known that its claims about the Saliva Kits were fraudulent and likely to deceive the public, including Plaintiffs and the putative Class Members, into believing that the Saliva Kits have uses and benefits that they do not possess.

72. Plaintiffs purchased Saliva Kits in reliance on Defendant's unfair and fraudulent representations about the kits. Plaintiffs would have foregone purchasing Defendant's product had they known that the Saliva Kits were unreliable and did not possess the health and other benefits that Defendant's advertisements attributed to them.

73. Plaintiffs and the putative Class Members' injuries are substantial and not outweighed by any real benefits to consumers or competition. Plaintiffs and the Class Members could not reasonably have avoided the information because Defendant intentionally misled the consuming public by means of the claims made with respect to the Saliva Kits as set forth herein.

74. In addition, Defendant's use of various forms of advertising media to advertise, call attention to, or give publicity to the sale of goods or merchandise which are not as represented in any manner constitutes unfair competition; unfair, deceptive, untrue, or misleading advertising; and an unlawful business practice within the meaning of the California law.

75. Defendant's wrongful business practices and procedures constituted, and constitute, a continuing course of conduct of unfair competition.



76. As a result of the foregoing acts, omissions, and practices, Plaintiffs and the putative Class Members have suffered actual damages as described herein.

77. Pursuant to Section 17203 of the California Business & Professions Code, Plaintiffs and the putative Class Members seek an order of this Court enjoining Defendant from continuing to engage, use, or employ its unfair and fraudulent practice of advertising the sale and use of the Saliva Kits products. Likewise, Plaintiffs and the putative Class Members seek an order requiring Defendant to cease making the unfair and fraudulent claims about its Saliva Kits that are described herein. Plaintiffs also request an order awarding Plaintiffs and the Class restitution of the money wrongfully acquired by Defendant by means of responsibility attached to Defendant's false and misleading representations.

#### **COUNT IV**

##### **Violations of California Consumer Legal Remedies Act (“CLRA”) CAL. CIV. CODE §§ 1750 et seq.**

78. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

79. Defendant is a “person” within the meaning of CAL. CIV. CODE § 1761.

80. Plaintiffs and the putative Class Members are “consumers” within the meaning of CAL. CIV. CODE § 1761.

81. Plaintiffs purchased Saliva Kits from Defendant for personal, family, or household purposes. The purchases of the Saliva Kits by Plaintiffs and the putative Class Members were and are “transactions” within the meaning of CAL. CIV. CODE § 1761.

82. Defendant’s marketing, labeling, advertising, and sales of the Saliva Kits violated the CLRA in at least the following respects:

- a. Defendant represented that the Saliva Kits have characteristics, ingredients, uses, and benefits which they do not have;
- b. Defendants represented that the Saliva Kits are of a particular standard, quality, or grade, which they are not;

- c. Defendant advertised the Saliva Kits with an intent not to sell the Saliva Kits as advertised; and
- d. Defendant represented that the subject of the sale of the Saliva Kits has been supplied in accordance with a previous representation when it has not.

83. Defendant's actions as described herein were done with conscious disregard of Plaintiffs' and the Class Members' rights, and Defendant was wanton and malicious in its concealment of the same.

84. Defendant's wrongful business practices constituted, and constitute, a continuing course of conduct in violation of the CLRA because Defendant is still representing that the Saliva Kits have characteristics and abilities which they do not have.

85. Pursuant to Civil Code § 1782, Plaintiffs will notify Defendant in writing by certified mail of the alleged violations of section 1770 and demand that the same be corrected.

86. Any waiver of a claim under the CLRA by Plaintiffs and/or the putative Class Members is unenforceable and void.

87. As a result of the foregoing acts, omissions, and practices, Plaintiffs and the putative Class Members have suffered actual damages as described herein, and these Class Members are entitled to recover such damages, together with punitive damages, equitable relief, injunctive relief, diminution of value, and reasonable attorneys' fees.

### **COUNT V**

#### **CAL. CIV. CODE §§ 1709, 1710**

#### **Deceit by Concealment**

88. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

89. Defendant made material representations and omissions to the general public, including Plaintiffs and the putative Class Members about the Saliva Kits that were false and misleading.

90. Defendant knew that its representations about the Saliva Kits were untrue or it did not have sufficient knowledge to warrant belief that it was true. Defendant made these false

representations with intent to induce Plaintiffs and the putative Class Members to act in reliance thereon.

91. Defendant willfully deceived Plaintiffs and the putative Class Members by concealing the true facts concerning the Saliva Kits. Defendant knew in advance of Plaintiffs and the Class Members' use of the Saliva Kits and of the lack of scientific validity associated with the Saliva Kits

92. Plaintiffs and the putative Class Members reasonably believed that Defendant's representations about the Saliva Kits were true, and in reliance on those representations, Plaintiffs and the putative Class Members purchased a Saliva Kit from Defendant.

93. Plaintiffs would have foregone purchasing Defendant's product had they known that Saliva Kits were unreliable and did not possess the health and other benefits that Defendant's advertisements attributed to it.

94. As a result of the foregoing acts, omissions, and practices, Plaintiffs and the putative Class Members have suffered actual damages as described herein, and these Class Members are entitled to recover such damages, together with punitive damages, equitable relief, injunctive relief and reasonable attorneys' fees.

## **COUNT VI**

### **Breach of Warranty of Merchantability and Fitness for a Particular Purpose**

95. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

96. Defendant developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Saliva Kits and, in the course of same conduct, directly advertised or marketed the Saliva Kits to the FDA and consumers.

97. Defendant impliedly warranted that its Saliva Kits were of merchantable quality and fit for the ordinary, common, and intended uses for which the product was sold.

Specifically, Defendant falsely impliedly warranted that the Saliva Kits could be used to, among other things, identify genetic health risks, and find out if consumers' children are at risk for inherited conditions.

98. Defendant knew, or had reason to know that consumers, including Plaintiffs and the putative Class Members, purchased the Saliva Kits for purposes described above.

99. Defendant knew, or had reason to know that consumers, including Plaintiffs and the putative Class Members, were relying on its skill and judgment to select or furnish a product that was suitable for the particular purposes.

100. Defendant breached its implied warranties of the Saliva Kits product sold to Plaintiffs and the putative Class Members because the product was not fit for the particular purposes described above.

101. As a direct and foreseeable result of the foregoing acts, omissions, and practices, Plaintiffs and the putative Class Members have suffered actual damages as described herein, and these Class Members are entitled to recover such damages, together with punitive damages, equitable relief, injunctive relief, diminution of value, reasonable attorneys' fees, costs of suit, and such other relief set forth herein.

## **COUNT VII**

### **Negligent Misrepresentation**

102. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

103. Defendant made misrepresentations to Plaintiffs and the putative Class Members, including without limitation, the misrepresentation that the Saliva Kits were effective, scientifically sound and valid, and could provide consumers with reliable health-related information.

104. Defendant made the foregoing representations without reasonable grounds for believing them to be true. These representations were made directly by Defendant and its authorized agents on the Saliva Kits packaging and in publications and other written materials

directed to the public with the intention of inducing reliance and the purchase and use of the Saliva Kits.

105. The representations by Defendant were in fact false and made with the intention of inducing reliance resulting in the purchase and use of the Saliva Kits.

106. In reliance on the above misrepresentations by Defendant, Plaintiffs and the putative Class Members were induced to purchase and to use the Saliva Kits. If Plaintiffs and the Class Members had known of the true facts and the facts concealed by Defendant, Plaintiffs would not have purchased or used the Saliva Kits.

107. Plaintiffs' reliance on the misrepresentations by Defendant was justified and reasonable in that such misrepresentations were made by individuals and entities that held themselves out as experts in the field of DNA testing and were in a position to know the actual facts.

108. As a result of the foregoing acts, omissions, and practices, Plaintiffs and the putative Class Members have suffered actual damages as described herein, and these Class Members are entitled to recover such damages, together with punitive damages, equitable relief, injunctive relief, diminution of value, reasonable attorneys' fees, costs of suit, and such other relief set forth below.

### **COUNT IX**

#### **Unjust Enrichment**

109. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

110. As a result of their unlawful conduct described above, Defendant was unjustly enriched.

111. Defendant has benefited from their unlawful acts and it would be inequitable for Defendant to be permitted to retain any of the ill-gotten gains resulting from payments made by Plaintiffs and the putative Class Members in reliance on their false, misleading, and unlawful representations about the health and other benefits of the Saliva Kits.

112. Plaintiffs and the putative Class Members' are entitled to the amount of Defendant's ill-gotten gains resulting from their unlawful, unjust, and inequitable conduct.

113. Plaintiffs and Class Members may have no adequate other remedy at law.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs prays for judgment against Defendant as follows:

1. For an order certifying that the action may be maintained as a class action, certifying Plaintiffs as representative of the Class, and designating their attorneys as Class counsel;
2. For an award of equitable relief as follows:
  - a. Enjoining Defendant from making any claims for the Saliva Kits found to violate California law as it is defined by and coterminous with FDA rules, regulations, and pronouncements, as set forth above, and
  - b. Requiring Defendant to make full restitution of all monies wrongfully obtained as a result of its conduct;
3. For actual damages in an amount to be determined at trial;
4. For an award of attorneys' fees;
5. For actual, statutory, and punitive damages as may be provided for by statute if the demanded corrections do not occur within the thirty (30) day notice period;
6. For the costs of this suit;
7. For pre- and post-judgment interest on any amounts awarded; and
8. For such further relief as may be just and proper.

### **DEMAND FOR JURY TRIAL**

Plaintiffs demand a jury trial on all issues so triable.

DATED: December 19, 2013

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